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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/605,406	09/29/2003	Derek Wayne Cornelius	03176-1-001000	2405

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EXAMINER
CLAYTOR, DEIRDRE RENEE

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
10/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/605,406	CORNELIUS ET AL.	
	Examiner	Art Unit	
	Renee Claytor	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response filed on 8/10/2007 is hereby acknowledged. The addition of new claims 14-21 is also acknowledged.

Applicant's arguments over the 35 USC 102 rejection over Krieder has been fully considered and the arguments are not found persuasive. Applicants argue that Krieder fails to teach anything with respect to reducing appetite or food intake as stated in claims 8-13. In contrast, Krieder teaches a study in which forskolin was administered to sedentary overweight females in which the females were shown to lose body weight and it is stated that "subjects who took forskolin tended to feel less fatigue and hunger and more of a feeling of fullness", which indicates that the subjects had less of an appetite for food. Further, Krieder goes on to discuss that the administration of forskolin may affect some psychological perceptions of hunger. Therefore, Krieder teaches reports of less of an appetite for food which will inherently lead to reduced food intake, after administration of forskolin. Applicants further argue that Krieder cannot teach an effective amount of forskolin to achieve these effects and the dose taught by Krieder was 50 mg. Krieder meets the limitation of claim 11 as rejected previously, because this dose falls within the range of that listed in the claim. Therefore the 35 USC 102 rejection is maintained.

Applicants argue over the 35 USC 103 rejection and assert that Krieder fails to teach all of the elements of the present claims and teaches away from the present invention. This argument is not persuasive because Krieder teaches the administration of one dosage level per day; however, it would be obvious to vary or optimize the dose

of forskolin to achieve the desired effect, such as the reduction of food intake and appetite for food and subsequent weight loss. Therefore, the teachings of Krieder render the dosage range of claim 12 obvious and the 35 USC 103 rejection is maintained.

Due to Applicants addition of new claims, the following modified rejections are being given below.

Objections

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: there is no signature by Applicants.

Claim Rejections – 35 USC 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8-11, 13, 18 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Kreider (*Muscular Dev*. 39(2), 260-262, 2002).

Kreider teaches administering forskolin in a capsule to control body weight, and decreasing the feeling of hunger and more of a feeling of fullness, without adverse side effects such as increased heart rate and blood pressure (meeting the limitations of claims 8-9 and 13). Kreider teaches that forskolin is derived from Coleus forskohlii (meeting the limitation of claim 10). Kreider reports studies conducted in which forskolin was given at a 250 mg dose (meeting the limitation of claim 11).

Claim Rejections – 35 USC 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 12-21 rejected under 35 U.S.C. 103(a) as being unpatentable over Kreider (*Muscular Dev.* 39(2), 260-262, 2002) as applied to claims 8-11, 13, 18 and 21 above.

Kreider teaches administration of forskolin to control body weight without adverse side effects.

Kreider does not teach administration of forskolin at a dose of 75 – 150 mg or the exact dosing regimen taught in claims 15-16.

Accordingly, it is obvious to vary and/or optimize the amount of forskolin provided in the composition, according to guidance provided by Kreider, in an effort to provide a composition having the desired properties such as the desired concentration of

forskolin. It would be further obvious to optimize the dosing regimen in an effort to maximize when forskolin will be most effective, in this case Kreider teaches administration of forskolin twice a day and it would be obvious to administer the doses in the morning and afternoon/evening or before a meal for the composition to have its maximal effect. One would be motivated to optimize the dose of forskolin and the dosing regiment to effectively reduce food intake and appetite for food, and subsequently weight loss. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is 571-272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER